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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,139	05/20/2002	Michael Anthony Cawthorne	0380-P02773USO	6237
110	7590	07/08/2005	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN			SAUNDERS, DAVID A	
1601 MARKET STREET			ART UNIT	
SUITE 2400			PAPER NUMBER	
PHILADELPHIA, PA 19103-2307			1644	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/019,139

Applicant(s)

CAWTHORNE ET AL.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 44-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39, 44-57 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

The claims pending are 1-39 and 44-57.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-39, drawn to methods of screening for agents for treating pancreatic islet or beta cell dysfunction.

Group II, claim(s) 44-45 and 50, drawn to methods of treating pancreatic islet or beta cell dysfunction

Group III, claim(s) 46-49, drawn to methods of determining the nature / degree of pancreatic islet or beta cell dysfunction.

Group IV, claim(s) 51-52, drawn to a method used to select an appropriate therapy for pancreatic islet or beta cell dysfunction.

Group V, claim(s) 53-56, drawn to proteins.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The screening method of Group I does not synthesize the agents that are selected and that would be used in the treating agents existed per se, prior to their further characterization by the screening method of Group I.

Group I does not synthesize the agents that are selected and that would be used in the treating method of Group II. These agents existed per se, prior to their further

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characterization by the screening method of Group I. They are only described by their Functional characteristics, not by their structural characteristics. This description of the agents that would be used in the method of Group II is inadequate. Since these agents, which would be the common technical feature that unites Groups II, and I have not been described and already exist (i.e. these agents cannot represent applicant's contribution over the prior art); there is no feature that provides for unity of Invention for Groups I and II.

The examiner further notes that the claims of Group II were not examined by the IPEA. These claims will not be examined with those, which have been examined by the IPEA.

The inventions listed as Groups I and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: It is noted that the IPEA has determined that the claims of Group III lack novelty. These claims thus provide no contribution over the prior art and thus do not have a unity of invention.

The inventions listed as Groups I and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The method of Group IV does to identify an "agent", as in Group I. Further the IPEA did not examine the claims of Group IV. These claims will thus not be examined with those which the IPEA has examined. It is also noted that the IPEA found the claims of Group I to lack

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an inventive step. Since these claims thus do not provide a contribution over the prior art, no other Group has unity of invention with Group I.

The inventions listed as Groups I and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The proteins of Group V do not constitute any "agent" identified by the method Group I. There is thus no unity of invention. Also, since Group I does not provide a contribution over the prior art no other Group has unity of Invention with Group I.

The examiner further notes that the IPEA did not examine the claims of Group V. These claims will not be examined with those which have been examined by the IPEA.

In the event applicant elects Group V, the following election of species is required:

- 1) Each of the individual proteins (POM 6, POM 7, etc.) recited in claim 54).

Claim 57 is a new claim, entered at the present national stage, and not examined by the IPEA. The examiner thus need not address whether this claim does or does not have unity with any of the other claims. In the event that applicant wants to prosecute the inventions of claim 57, the following further restriction requirement holds.

Group VI, claim(s) 57, drawn to a treatment method with protein POM 6.

Group VII, claim(s) 57, drawn to a treatment method with POM 7.

Group VII, claim(s) 57, drawn to a treatment method with POM 8.

Group IX, claim(s) 57, drawn to a treatment method with POM 9.

Group X, claim(s) 57, drawn to a treatment method with POM 10.

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Group XI, claim(s) 57, drawn to a treatment method with PMT 1.

Group XII, claim(s) 57, drawn to a treatment method with POMT 2.

Group XIII, claim(s) 57, drawn to a treatment method with POMT 3.

Group XIV, claim(s) 57, drawn to a treatment method with POMT 4.

Group XV, claim(s) 57, drawn to a treatment method with POMT 5.

Group XVI, claim(s) 57, drawn to a treatment method with POMT 11.

Group XVII, claim(s) 57, drawn to a treatment method with POMT 12.

Group XVIII, claim(s) 57, drawn to a treatment method with POMT 13.

Group XIX, claim(s) 57, drawn to a treatment method with POMT 14.

Group XX, claim(s) 57, drawn to a treatment method with POMT 15.

The inventions listed as Groups VI - XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each invention represents a treatment with a unique protein. Since each protein has its own unique pI and m.w., as well as other structural features, the appropriateness of one of these particular proteins for use in a treatment method would not suggest that any of the other proteins would be appropriate for use in a treatment method.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR  
June 30, 2005

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644